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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/080,965      | 02/22/2002  | Peter T. Cheng       | LA29A DIV-1         | 2484             |

23914 7590 03/25/2003

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1626

DATE MAILED: 03/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

|                               |                                       |
|-------------------------------|---------------------------------------|
| Application No.<br>10/080,965 | Applicant(s)<br>PETER T. CHENG ET AL. |
| Examiner<br>EBENEZER SACKY    | Art Unit<br>1626                      |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Mar 14, 2003.

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-5, 9, 10, 13-15, 17, 33-35, 37, 39, 40, and 50 is/are pending in the application.

4a) Of the above, claim(s) 37, 39, 40, and 50 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) \_\_\_\_\_ is/are rejected.

7)  Claim(s) 1-5, 9, 10, 13-15, 17, and 33-35 is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2

6)  Other:

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## **DETAILED ACTION**

### **Receipt of the Preliminary amendment and Information Disclosure**

Statement filed on 02/22/02 is acknowledged and has been entered into the file. Claims 1-54 were pending. Claims 6-8, 11-12, 16, 18-32, 36-37, 41-49 and 51-54 have been canceled. Accordingly, claims 1-5, 9-10, 13-15, 17, 33-35, 37, 39-40 and 50 are pending.

### ***Specification***

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point

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out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-5, 9-10, 13-15, 17 and 33 are, drawn to compounds and composition, classified in class 546 and 514, in various subclasses .
  - II. Claims 34-35 are, drawn to method of using compounds of claim 1, classified in class 514, subclass 336+.
  - III. Claims 37, 39-40 and 50 are, drawn to pharmaceutical combinations, classified in class 514, in various subclasses.
2. The inventions are distinct, each from the other because of the following reasons: the inventions of groups I-III are independent and distinct

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because there is no patentable co-action among the various groups and a reference anticipating one member will not render another obvious.

3. Inventions I, III and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P.. § 806.05(h)). In the instant case the process as claimed can be practiced with another materially different product such as shown in U.S. Patent No. 5,739,135 where it is disclosed that compounds having a pyridine nucleus linked by a suitable linker to hypolipidemic agents are suitable for lowering blood serum cholesterol.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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5. This application contains claims directed to the following patentably distinct species of the claimed invention: various heterocycles such as oxazoles, pyridines, thiazoles etc.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, there are numerous species disclosed in the Tables and Examples defined throughout the specification.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

With the election of a single disclosed species, the Examiner will identify a generic concept inclusive of said elected species for examination

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along with said elected species. The compounds will be so similar thereto as to be within the same inventive concept and reduction to practice.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP.....  
§ 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. During a telephone conversation with Burton Rodney on 01/09/03 a provisional election was made with traverse to prosecute the invention of

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Group I, claims 1-5, 9-10, 13-15, 17 and 33 and species of Example 457 and 458. Affirmation of this election must be made by applicant in replying to this Office action. Claims 34-35, 37, 39-40 and 50 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

The method of use claim(s) will be rejoined with the compounds and composition claim(s) if the claims are commensurate in scope therewith.

The following generic concept as depicted in claim 1 is identified for examination along with the elected embodiment: Q is C; A is O; Z is O; X is N; R<sup>1</sup> is H or lower alkyl; R<sup>2</sup> is H or lower alkyl; R<sup>2a</sup>, R<sup>2b</sup>, R<sup>2c</sup> each is H or lower alkyl; R<sup>3</sup> is aryloxyarylalkyl, arylalkoxyarylalkyl and

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alkylaryloxyarylalkyl; Y is CO<sub>2</sub>R<sup>4</sup>, where R<sup>4</sup> is H or alkyl; x is as defined; m is as defined; n is as defined; each of R<sup>2a</sup>, R<sup>2b</sup> and R<sup>2c</sup> is H or alkyl. The remaining subject matter of claims 1-5, 9-10, 13-17, 20 and 33 (in part) in their entirety stands withdrawn from further consideration under 37 CFR 1.142(b) as constituting other patentably distinct inventions.

The withdrawn subject matter of claims 1-5, 9-10, 13-15, 17, 33-35, 37, 39-40 and 50 (in part) in their entirety is properly restricted as said subject matter differs in structure and element from the elected subject matter so as to be patentably distinct therefrom, i.e. a reference anticipating the elected subject matter would not even render obvious the withdrawn subject matter and fields of search are not co-extensive.

Claims 1-5, 8-10, 13-17, 20, 33-35, 37, 39-40 and 50 in their entirety are objected to as containing non-elected subject matter identified supra.

It is suggested that the plural phrase "salts thereof", claim 1, page 3, line 1 of the preliminary amendment filed on 02/22/02, be replaced with the singular phrase "salt thereof".

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WO 01/21602 A1 is cited to show the state of the art.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (703) 305-6889. The examiner can normally be reached on Monday-Friday from 7:30 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

EOS

March 24, 2003

Joseph K. M. Kane

Joseph K. McKane

Supervisory Patent Examiner

Art Unit 1613, Group 1600

Technology Center 1